# 509 Asphalt Binder Quality Management System

# **509.01 Scope**

This standard specifies requirements and procedures for a certification system that is applicable to all suppliers of performance graded asphalt binders (PGAB). The requirements and procedures cover materials manufactured at refineries and/or materials.

This standard may involve hazardous materials, operations, and equipment. It does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

### **509.02 Referenced Documents**

**AASHTO Standards:** 

M 320	Specifications for Performance Graded Asphalt Binder
R 18	Establishing and Implementing a Quality System for Construction Materials Testing Laboratories
R 26	Certifying Suppliers of Performance-Graded Asphalt Binders
R 29	Practice for Grading or Verifying the Performance Grade of an Asphalt Binder
T 40	Sampling Bituminous Materials
$T\ 301_{mod}$	Elastic Recovery Test of Bituminous Materials by means of a Ductilometer

#### **ASTM Standards:**

D 8 Terminology Relating to Materials for Roads and Pavements

D 3665 Practice for Random Sampling of Construction Materials

## 509.02 Terminology

Asphalt Binder: Asphalt based cementitious material that is produced from petroleum residue either with or without the addition of non-particulate organic modifiers to add quality and consistency for direct use in the manufacture of bituminous pavements.

ASC: Approved Supplier Certification

*PGAB*: Performance Graded Asphalt Binder

DSR: Dynamic Shear Rheometer

BBR: Bending Beam Rheometer

Supplier:

A supplier is defined as an individual or an entity that performs the final production, storage-for-resale, blending, or modification that alters the properties of the PGAB used in the M320 specification. A supplier could be a refinery, a terminal, or a Hot-Mix Asphalt (HMA) producer. If there is no further alteration of the PGAB after its initial production, the refinery is the supplier and must provide the certification. If there is any grade modification of the PGAB at the terminal, the terminal becomes the supplier and must provide the certification. If the PGAB is held for resale as PGAB and is re-branded by the terminal or HMA producer, the terminal or HMA producer becomes the supplier and must provide the certification.

*WCTG*:

Western Cooperative Test Group, a government and industry association.

NOTE 1- Various refining techniques can produce asphalt binders of equivalent grade. These asphalt binders may be incompatible with each other. Hot-mix producers should consider compatibility before combining different asphalt binders and/or asphalt binders from different sources. If different asphalt binders and/or asphalt binders from different sources are blended by the user, they become the responsibility of the Hot-mix producer.

Agency:

The Utah Department of Transportation. UDOT's Engineer for Asphalt Materials will be responsible for the certification of PGAB suppliers and for the final acceptance of the PGAB.

- Specification Compliance Testing: Complete testing according to the specification requirements of AASHTO M320, and Section 509.11, Table 1 of this plan. The procedure for verification of grade as described in AASHTO R 29 shall be followed.
- Specification Compliance Agent: The agent appointed by the supplier, and approved by the agency who's authorized signature binds the supplier. I e.: AMRL laboratory manager.
- QC Testing: Quality Control testing could be a subset of the M320 testing that the supplier will select and describe in his Quality Control Plan. The supplier QC plan will have to be approved by the agency or its authorized representative.
- Qualified Technician: A technician with the experience, skills, and knowledge to manage the testing, and documentation necessary in a quality control laboratory. Validation of the qualified technician will come from the UDOT's Engineer for Asphalt Materials. The agency will observe the Specification Compliance testing of at least one monthly split sample per year. The agency will test their portion of the split; correlate the data and comment on any testing deficiencies noted. Technician Qualification will be modeled after criteria from the Asphalt Institute.
- Statistical Quality Control: A product will be said to be in statistical quality control when the following occurs:
  - Specification Compliance Tests are accomplished on three successive binder production units (the production unit size is to be agreed upon by the agency). Use the three test values obtained immediately prior to the time a decision is being made.
  - The Mean and sample standard deviation of each value in the three specification compliance tests is calculated as follows:

$$Mean = \overline{x} = \frac{\sum x}{3}$$

where x is an individual test result. ie.  $G^*$ 

Sample Standard Deviation = 
$$s = \sqrt{\frac{\sum (x - \overline{x})^2}{2}}$$

• A quality limit is established for the test being analyzed. This may be an upper limit  $Q_u$  or a lower limit  $Q_1$ .

 $Q_u = (T_u - Mean)/s$  and

 $Q_1 = (Mean - T_1)/s$ 

where  $T_u = Upper Specification Limit and$ 

 $T_1$  = Lower Specification Limit

- The value of  $Q_u$  or  $Q_1$  must be greater than 1.1476 (representing 98% within limits for n = 3).
- Continuous Production/Live Tank: The method used to manufacture products without interruption. Modified asphalt continuous production may be small complete batches produced continually, then transferred to a larger sales tank, or small concentrated batches, then letdown-to-completion into the larger sales tank.
- Batch, or One Time Production/Static Tank: Batch production methods include, but not limited to small incomplete batches produced in concentrate, then transferred, letdown and completed into one large complete batch. This method will have the tank locked-out until testing is completed.

## 509.03 Significance and Use

This standard specifies procedures for minimizing disruption of PGAB shipments caused by testing requirements. This is accomplished by a certification system with quality control and specification compliance tests performed by the supplier on samples obtained prior to shipment.

The number of grades available under AASHTO M320, and Section 509.11, Table 1 of this plan may require construction of additional storage facilities to comply with the "sample and hold while testing" procedures.

This standard provides information and guidelines on the following:

- General requirements that the supplier must satisfy prior to achieving approved supplier status.
- Minimum requirements that must be included in a supplier 's quality control plan.
- General requirements that the agency must satisfy prior to certification.
- Procedural requirements for shipment of PGAB's under an ASC system.
- Procedural requirements for agency monitoring of an ASC system at the shipping facility.

# **509.04 Purpose**

The Asphalt Binder Quality Management System (ABQMS) provides the Utah Department of Transportation with a quality management program for Performance Graded Asphalt Binders (PGAB) by establishing qualified sources of these materials and verifying the compliance of materials shipped from these sources to paving projects with specification requirements.

The ABQMS is comprised of a Standard Practice for Certifying Suppliers of Performance Graded Asphalt Binders, a PGAB Asphalt Binder Quality Assurance Plan, and a method of addressing non-specification PGAB delivered to paving projects.

All asphalt binder producers and/or suppliers to UDOT paving projects must be registered by UDOT under the **Standard Practice for Certifying Suppliers of Performance Graded Asphalt Binders** as outlined under **Section 509.01.** 

The contractor will be responsible for the **Field Quality Control of PGAB** when the binder is delivered to the mix plant.

UDOT will accept asphalt binder under its **Performance Graded Asphalt Binder Quality Assurance Plan** as outlined under **Section 509.10.** 

The Calculation and Application of Price Reductions for Non-Specification PGAB section will address non-specification PGAB delivered to paving projects as outlined under **Sections 509.11**.

# **509.05** Testing and Accreditation Requirements

Specification Compliance Testing shall be performed in an AMRL accredited laboratory, by a Qualified Technician. The AMRL accredited laboratory will, at a minimum, be equipped with one Bending Beam Rheometer (BBR), one Dynamic Shear Rheometer (DSR), one Pressure Aging Vessel (PAV), one Brookfield Rotational Viscometer (RV) with Thermocell, one Rolling Thin film Oven (RTFO) and one Direct Tension (DT) device. The AMRL accredited laboratory will be certified to run the tests associated with this equipment and UDOT specification

A copy of the AMRL report on the lab inspection shall be provided with the testing results, accompanied by documentation of resolution of any discrepancies in the AMRL report. A copy of the report shall be supplied to UDOT Central Materials within 90 days of receipt of initial AMRL findings.

Cost of this inspection shall be borne by the source of data. Copies of all proficiency sample test reports received from AMRL, along with any required remediation shall be provided to UDOT's Central Materials within 90 calendar days of receipt of the final report.

Each supplier terminal supplying asphalt binder to UDOT is required to participate in WCTG round robin testing.

Specification Compliance Testing on a Continuous Production process must be completed in real time, as described in the suppliers Agency Plan, in an AMRL accredited laboratory, by a Qualified Technician. Set release parameters according to initial Quality Control, and Specification Compliance testing experience. Initial production units must be subjected to Specification Compliance Testing. Once release parameters are set, Specification Compliance testing will be conducted at least once per week, per product. Once Statistical Quality Control is established, and maintained Specification Compliance Testing can be reduced to once every other

week, per product.

Batch production testing must be completed on the finished, stable product. This product must be held for Specification Compliance Testing before being released for delivery. Once the product meets all Specification Compliance requirements and released for delivery, additional Specification Compliance testing must be completed at least every other week, or when additional material is added to the tank.

## **509.06 Supplier Requirements**

The supplier shall submit annually, prior to the paving season, a written request to the agency for authorization to ship PGAB's under the ASC system and shall list the grades to which the request applies. The written request shall be accompanied by 30, one-gallon containers of each grade of PGAB with applicable certified test results covering all specification parameters. These samples shall represent actual formulations for use in mix design verification, and shipped during the paving season. The agency will certify the binder grade from these samples. Any subsequent formulation changes will require prior shipping approval and a new mix design.

The agency (or its representative) shall have access at all times to the suppliers production/shipping facility, to inspect the facility, to observe the suppliers production, and production/quality control procedures, to obtain samples, and to perform tests.

The supplier shall submit to the agency, for approval, a complete quality control (QC) plan that complies with these requirements before March 31 of each calendar year.

The supplier shall follow the procedures set forth in the approved QC plan.

The supplier shall establish and maintain a daily record of all tests required on each grade included in the written request. This record, if requested, shall be made available to the agency.

The supplier shall submit the test results in a format that can be easily understood by a technician with minimum training in performance-graded binder testing. The system of units used shall be clearly stated. If test results are presented in a tabular format, the units, where applicable, shall be stated either as part of a column heading or after the description of the physical parameter or after its numerical value.

The supplier shall also furnish the raw test data in an electronic, Microsoft compatible format or in any commonly used spreadsheet format upon request by the agency.

The supplier shall submit all reports required by this standard in a format approved by the agency.

The supplier shall have a satisfactory record of compliance with specifications.

The shipments of product to UDOT projects shall be accompanied by two copies of the shipment bill of lading which shall include (1) the name and location of the supplier, (2) the grade of the material, (3) the quantity of the material shipped, (4) the date of the shipment, (5) a statement certifying that the transport vehicle was presented by the carrier acceptable for the material shipped. A Certificate of Compliance signed by the suppliers "Specification Compliance Agent". A complete Material Safety Data Sheet (MSDS) as required by the Code of Federal Regulations shall be available for each shipment.

# 509.07 Supplier Quality Control (QC) Plan (Minimum Requirements)

The supplier QC plan shall identify:

The type of facility (i.e., refinery, terminal, etc.)

The location of the facility,

The location of the AMRL accredited laboratory responsible for Specification Compliance Testing,

The name(s), and telephone number(s) of the Qualified Technician(s) responsible for quality control at the facility,

The Quality Control (QC) tests to be performed on each PGAB,

The laboratory(s) performing quality control tests (if different from the accredited lab) on the binder(s) that are shipped,

The name(s) of the Specification Compliance Agent.

The supplier QC plan shall include a declaration stating that if a test result indicates non compliance of any shipment with the purchase specifications, the supplier shall (1) immediately notify the agency of the shipment in question, (2) identify the material, (3) cease additional shipment until material is brought back to specification, (4) notify the agency when shipment shall resume, (5) implement any mutually agreed-upon procedures for the disposition of the non compliance material.

The supplier QC plan shall describe protocols and frequency for Quality Control, and Specification Compliance testing.

Describe in detail the method(s) for obtaining asphalt binder samples. The described method must assure that the asphalt binder sample is representative of the contents of the entire tank being sampled.

Specification compliance testing (complete AASHTO M320 testing including AASHTO T- $301_{mod}$ ) shall be performed for at least three consecutive production units until statistical quality control is achieved. The supplier and the agency will agree to the size of a production unit. The agency must approve any change to production units.

NOTE 2- Do not produce modified binders at the hot-mix production site. Modified binders shall be produced at a refinery or terminal.

NOTE 3- The compliance criterion for Failure Stress and Strain in the Direct Tension Test is for those PG Grades having an algebraic difference between the high and low design grade of 92°C or greater. G\* denotes the complex modulus.

NOTE 4 - the compliance criterion for elastic recovery is for grades having an algebraic difference of 92°C or greater between the high and low temperatures.

After statistical quality control is achieved and with the approval of the agency, the frequency of testing can be further reduced.

If any Specification Compliance criteria is not met, or after a plant shut-down, every production unit will be tested for full Specification Compliance until Statistical Quality Control is again met.

Quality Control testing guidelines for manufacturer- At least two AASHTO M 320 including T  $301_{mod}$  tests shall be used for monitoring high and low temperature properties of the binder. Manufacturers may use non-AASHTO M320 tests approved by the agency. The use of non-AASHTO M320 tests does not preclude the need to meet AASHTO M320 specifications or to run complete AASHTO M320 tests.

The QC plan shall include a statement that the supplier, if requested by the agency, shall prepare and submit monthly summary reports of all quality control and specification compliance tests performed during that period.

In order to prevent contamination of shipments, the supplier QC plan shall provide an outline of the procedure(s) to be followed for inspection of transport vehicles prior to loading. The procedure shall include an entry stating that the transport vehicle inspection report, signed by the responsible inspector, shall be maintained in the supplier's records and will be made available for review by the purchaser/agency upon request.

The supplier shall include the procedures and policies in place to prevent/eliminate the loading/delivery of material(s) non-specified for a given UDOT project. This section will outline in detail the procedure(s) for proper product loading. The procedure(s) shall detail all means established to eliminate the mis-loading of asphalt binders.

# **509.08 Agency Requirements**

The agency shall review the QC and may visit the shipping site.

The agency, upon receipt of the application for **ASC** status, shall review the application, and if acceptable, notify the supplier of its approval. The notification shall include a listing of the grades covered.

The agency shall verify that the supplier's testing laboratory(s) has current AASHTO accreditation and participates in the WCTG round robin testing program.

The agency shall authorize shipment of each listed performance graded binder under the ASC system only after all requirements of the ASC have been satisfied.

## 509.09 Split Sample Testing

All test samples required by this standard shall be obtained in accordance with AASHTO T 40, ASTM D3665, or as described in the agency plan. The use of stratified random sampling procedure is important for the establishment of a valid certification program.

The agency will test split samples that are obtained at random from the Supplier's facility.

# NOTE 5- Split samples shall be obtained from the same general locations from which the Supplier's samples are taken.

The agency shall determine the frequency of split sample testing. At least one split sample shall be taken and tested every 30 days. Results from the split sample testing shall be supplied to UDOT's Central Materials Laboratory no later than 14 days from the date of sampling.

If the split sample data and the Supplier test data are not within the following tolerances, (percent difference from the average) an immediate investigation shall be conducted to determine the cause of the difference between the data:

Original DSR: ±10% RTFO DSR: ±11% PAV DSR: ±23%

Original phase angle  $\pm 2^{\circ}$  s (60 sec), BBR:  $\pm 10\%$  m-value, BBR:  $\pm 0.015$  Failure Strain, DT:  $\pm 30\%$  Failure Stress, DT  $\pm 20\%$ 

Elastic Recovery of RTFO Residue ± 10%

Unless available facts indicate otherwise, the investigation shall include a review of sampling and testing procedures of both supplier and agency.

## 509.10 Performance Graded Asphalt Binder Quality Assurance Plan

# **UDOT** Sampling Procedures

Each day that asphalt concrete is being produced, a binder sample, comprised of a minimum of three (3) individual one (1) quart containers will be taken at random times from the mix plants asphalt tank injection line. CAUTIONS GIVEN: A UDOT inspector must witness the sample being taken. Two of these containers will be for UDOT's use and the other container will be given to the contractor. The contractor will retain his samples until project completion. Each sample will be taken from the sampling valve after sufficient amount of binder is run out and wasted, in order to clear any residual asphalt binder and/or solvent that may build up in the sampling valve. It is the Contractor's responsibility to dispose/recycle accumulated wasted asphalt binder in a manner that will satisfy EPA requirements. Each sample will be taken at random times during the production day as determined by UDOT.

If mix plant operations are suspended for more than 48 hours, the next asphalt binder sample will not be taken randomly; instead, this asphalt binder sample will be taken at the resumption of operations.

# Binder Lots and Binder Sublots

Each day's mix production shall constitute a binder sublot sample (represented by one random sample) and each week's mix production shall constitute a binder lot sample. A week shall be defined as three (3) days before, and three (3) days after the date of the binder sublot sample. A binder lot sample, however, will not exceed eight (8) binder sublot samples.

Thus the tonnage of binder may vary from mix sublot to mix sublot and from mix lot to mix lot. If two (2) production mix sublots or less are accumulated within a production week, this will not be considered a binder lot. These mix sublots will be included within the next production week. Thus, a binder lot shall consist of at least three (3) sublots samples.

A binder sublot sample shall include only one grade. Thus, if the binder grade is changed within a production day, that day will be divided into binder sublot samples representing each binder grade used and one binder sample will be taken for each binder grade used.

At the end of the project, the final mix lot may include less than three binder sublot samples.

All binder sublot samples will be sampled and/or witnessed by a representative of the contractor and a UDOT inspector as stated in UDOT's Minimum Sampling and Testing Requirements, Section 02745. At the time the binder sample is taken, both parties, signifying each samples acceptability, will sign a sample identification form. The three binder sublot sample containers must be labeled identically. UDOT will take control of its portion of the sample once obtained. The contractor will take control of and retain its portion of the sample.

# **UDOT Testing**

UDOT's Regional Materials Representative will randomly choose one (1) binder sublot sample from each mix lot. This sublot sample will be tested completely, or partially by UDOT's AMRL accredited laboratory, or by an independent laboratory approved by the agency. If the tested grade complies with the specified grade, the binder lot will be accepted. If the grade does not comply with the specified grade, the Resident Engineer will be notified of the failure by means of a test report. This test report will also be sent by registered mail to the Binder Supplier.

## 509.11 Calculations and Application of Price Reductions for Non-specification PGAB

Table 1. Specifications, compliances and rejection limits for price rejection calculations for Performance Graded Asphalt Binders.

Property	Specification	Compliance Limit for Price Reduction of 0 %	Rejection Limit Price Reduction 25 %
G*/sind of the original PGAB at high grade temp, (kPa) (Rule of 86 or lower), degrees	1.00 Min	0.84 Min	0.70 Min

Property	Specification	Compliance Limit for Price Reduction of 0 %	Rejection Limit Price Reduction 25 %
G* of the original PGAB at high grade Temperature, (kPa)	1.30 Min	1.25 Min	1.11 Min
d (phase angle) of the original PGAB at high grade Temp. (Rule of 92), degrees	74.0 Max	75.0 Max	77.0 Max
d (phase angle) of the original PGAB at high grade Temp. (Rule of 98) degrees	71.0 Max	72.0 Max	74.0 Max
G*/Sind of RTFO Residue	2.20 Min	1.87 Min	1.53 Min
G* Sind of PAV Residue (kPa)	5000 Max	5250 Max	5700 Max
Stiffness of the PAV residue at Low Grade temp. + 10°C, (Mpa)	300 Max	311 Max	355 Max
Slope (m-value) of the Creep Curve at Low Grade temp. +10°C	0.300 Min	0.295 Min	0.266 Min
Failure Strain of PAV Residue in Direct Tension at Low Grade Temp. + 10°C1, %	1.500 Min	1.400 Min	1.200 Min
Failure Stress of PAV Residue in Direct Tension at Low Grade Temp. + 10°C¹, Mpa	4.00 Min	4.00 Min	3.50 Min

Property	Specification	Compliance Limit for Price Reduction of 0	Rejection Limit Price Reduction 25 %
Elastic Recovery of RTFO Residue <sup>1</sup> , % (Rule of 92) (Rule of 98) (Rule of 104)	65 Min 70 Min 75 Min	60 Min 65 Min 70 Min	50 Min 55 Min 60 Min

<sup>&</sup>lt;sup>1</sup> Use only for binders whose high and low temperature algebraic difference is 92 ° C or greater

If the value of the measured properties meet the compliance limit of table 1, the price reduction is 0% for each individual test property. The price reduction for each individual property will be 25% at the rejection limit. If any measured property is outside the rejection limit, i.e., greater than 25%, the mixture will be rejected. For each property whose value lies between the compliance limit and the rejection limit, the price reduction will be calculated assuming a linear variation between 0 and 25. For example, if the measured m value is 0.270, the per cent price reduction for the m-value will be calculated as follows:

$$25*\left(\frac{0.295-0.270}{0.295-0.266}\right)=21.6\%$$

For a particular sample having more than one parameter out of specification, the composite price reduction for the PGAB will be calculated by summing the reduction of each individual property calculated as described above.

The PGAB shall be accepted with reduced composite price reduction if none of the critical properties are outside the rejection limit and the composite price reduction is 25% or less. The material will be rejected if one or more of the measured properties fall outside the rejection limit or if the composite price reduction is more than 25%.

#### **509.12 Withdrawal of ASC Status**

The agency may revoke or suspend ASC status under the following conditions:

The test data provided by the supplier to the agency does not meet the tolerances shown in this section for three consecutive samples.

Failure to consistently supply material of a specific grade meeting specifications for three (3) acceptance samples as determined by UDOT test results in a 60 day period.

Supplier test data can't be verified repeatedly by the agency and the agency deems that it is due to negligence on the part of the supplier.

The supplier is not following the approved QC plan.

A visit by the agency's representative to the supplier's facility reveals significant quality control problems.

## **509.13 Appeal Procedures**

If the contractor wishes to appeal the binder test results of a mix lot, the contractor shall submit a written appeal request within 14 calendar days of *NOTIFICATION FROM THE ENGINEER*. The appeal must state the grounds or the circumstances of the appeal and if the test results are in-question, the appeal must be accompanied by all of the quality control test results that represent the lot in question. The contractor's retained and disputed sublot sample (see Section 509.10) must also be submitted to UDOT. An AMRL accredited laboratory, independent from the supplier and contractor, and mutually acceptable to the contractor and UDOT, or if acceptable to the contractor, UDOT's AMRL accredited laboratory, will test this sample for full specification compliance. The original testing laboratory will not test this sample. The contractor will be responsible for testing. The contractor will be held responsible for all penalties assessed if the contractor's part of the sample can't be furnished. The binder supplier is not to be held liable in this case.

The appeal request and the submitted test results will be reviewed by UDOT. If the appeal has merit and the contractor's binder test results from the mix plant indicate a significant difference between UDOT's binder test results, the appeal will be accepted by UDOT.

When an appeal is accepted, the agency will conduct additional binder tests on two (2) additional sublot samples from the lot in question. Two bracketed sub-lot samples will be tested for those test parameters that significantly differ between UDOT and the contractor. Bracketed is defined as the sublot samples just before, just after the failed sample. Any invalid test results will be disregarded. The initial and bracketed sublot sample test results for each test will be averaged and the average value for each test will be considered the final lot value. Thus, the final lot values will be used to determine compliance or non-compliance. Compliance or non-compliance will be acted upon as outlined in **Section 509.11**.

The contractor will be notified in writing of the additional test results, the final lot values, and the appeal conclusions.

If either of the additional bracketed sublot samples fails specification, the entire lot will be tested for specification compliance.

If a third sample from the lot in question fails specification compliance, all project sublot samples will be tested for specification compliance. An AMRL accredited laboratory approved by the agency will perform this additional "Quality Control" testing. Cost of this additional Quality Control testing will be the responsibility of the contractor. A third failure in any project sublot may be grounds for supplier decertification by the agency. Additional failures from these additional project sublots will be investigated and penalties assessed.

A breakdown in a suppliers Quality Control system, as described above will initiate an investigation of the supplier. This investigation will consist of Quality Control testing on all UDOT projects being supplied by the supplier in question using a like grade during the timeframe of any of the 3 failed sublot samples. Cost of this testing will be the responsibility of the agency. Additional failures from these additional projects will be investigated and penalties assessed.

If the appeal is not accepted, UDOT will submit a denial letter to the contractor, stating the grounds for the denial.

The contractor may request referee testing on the assessed price reductions. The contractor will agree to have the available back-up sublot samples retained by UDOT, from the lot in question, tested by an AMRL accredited laboratory mutually acceptable to the contractor and UDOT. All specification parameters in contention will be tested on each sublot sample. The contractor will agree to bear the costs of testing each sublot sample if the referee tests verify non-specification compliance on any one-sublot sample. UDOT will bear the costs of testing if all sub-lot samples are in compliance to the specifications. The AMRL accredited laboratory will report the results to UDOT. The results of the tests will be binding to both parties. These test results for the test parameter(s) in contention will be averaged. This average value(s) will be considered the final lot value. This final lot value(s) will be used to determine compliance/non-compliance to the specifications.